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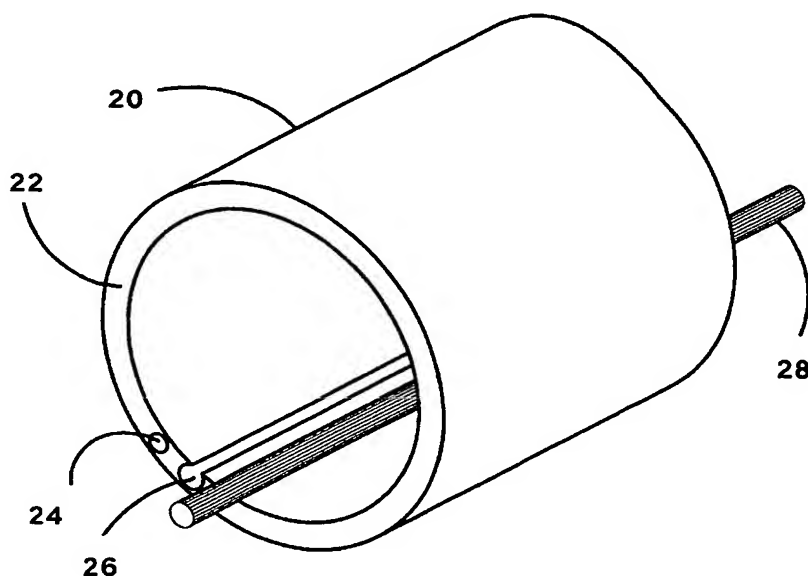
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(54) Title: TUBE FOR INSPECTING INTERNAL ORGANS OF A BODY



(57) Abstract: An inspection tube (20) for use in the medical practice, in which sensors, such as a miniature electronic camera, are incorporated in the distal face of the tube. The sensors receive energy supplied via conduits (24, 26, 28) running along the length of the tube, preferably embedded within the wall. Signals of the sensors are transmitted to the rear of the tube where they are fed into receivers. Sensor cleaning can be affected in some embodiments by conducting cleaning agents through a channel in the wall of the tube. An alarm procedure can be affected by comparing sensed pattern with a reference base pattern and defining a critical deviation from the reference base.

TUBE FOR INSPECTING INTERNAL ORGANS OF A BODY

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TECHNICAL FIELD OF THE INVENTION

The present invention relates generally to a medical means of monitoring critically ill and anesthetized patients including monitoring ventilated patients. More specifically, the invention is a device for monitoring patient's organs and cavities.

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BACKGROUND OF THE INVENTION

Insertion of tubes into patient's body organs, cavities and tracts is a common procedure in emergency and critical care medicine. An endotracheal tube may be inserted into the trachea of a patient who is in acute respiratory failure or is undergoing general anesthesia. The endotracheal tube must be placed quickly and accurately and positioned with its tip in the mid portion of the patient's trachea to prevent accidental slipping and to provide proper seal and ventilation of both lungs. Similarly, a naso - gastric tube is commonly inserted through the nose or mouth into the stomach of patients who need artificial feeding or evacuation of the content of the stomach. Another tube that is frequently inserted into a body cavity during emergency treatment is the urinary catheter. This catheter is threaded through the urethra into the urinary bladder. The correct placement of these tubes and catheters throughout their use is critically important.

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Many patients who are critically ill or undergoing general anesthesia require artificial ventilation. For over 40 years the most common method of providing artificial ventilation has been by pumping compressed air into the patient's lungs through an endotracheal tube. This tube is inserted through the patient's mouth
5 or nose and passed between the vocal cords into the trachea. Alternatively, a tube may be inserted into the trachea through a tracheotomy surgical incision.

For oral intubation the operator usually uses a laryngoscope, which consists of a handle and a blade. The operator inserts the blade into the patient's mouth and advances it until its tip lies in the pharynx beyond the root of the tongue.

10 The handle is then used to manipulate the blade and push the tongue out of the way until the epiglottis and the vocal folds can be seen. The tip of the endotracheal tube can then be aimed and pushed between the vocal folds into the trachea. This method of insertion is used in the majority of intubations, but requires skill, training and experience and is only performed by specialized
15 physicians and licensed paramedics.

An alternative method that is often used when difficult intubation is anticipated is over a fiber optic bronchoscope. First the bronchoscope is connected to a light source to provide the needed illumination of the field facing its tip. The shaft of the bronchoscope is then inserted through the endotracheal tube and
20 moved in as far as possible. The tip of bronchoscope is then inserted into the patient's airway and advanced under visualization through the bronchoscope's eyepiece or a video display in between the vocal folds into the trachea. The endotracheal tube can now be pushed down the bronchoscope shaft and moved between the vocal folds into the trachea. The endotracheal tube can
25 now be secured and the bronchoscope removed to free up the lumen of the

endotracheal tube. While the bronchoscopic method is safer than with the laryngoscope, the equipment needed is expensive, delicate and more cumbersome and is seldom found in the field or on emergency medical vehicles.

- 5 Securing the endotracheal tube and preventing its inadvertent movement during use is critical to the prevention of dire accidents. Inflating a cuff that surrounds the tube near its tip occludes the space between the outer wall of the tube and the inner wall of the trachea to provide an airtight seal. The cuff is connected to the external end of the endotracheal tube through a thin channel
- 10 in the tube's wall. The channel is connected to a one-way valve through which air can be injected to inflate the cuff to the desired pressure and volume. The cuff is also helpful in securing the tube in place, but additional fasteners are usually applied around the head to prevent the tube from slipping in or dislodging.
- 15 Once the tube has been inserted, it is mandatory to verify its correct position. Accidental insertion of the tube into the esophagus or placing it too deep inside the airways, so that its tip is lodged in one of the main stem bronchi instead of in the trachea may lead to catastrophic consequences and asphyxiation. Many methods are available to verify the endotracheal tube placement. Auscultation
- 20 of both sides of the chest is usually done to verify symmetric air entry into both lungs. A chest x-ray is another well-tested method of verifying the tube placement. The x-ray picture reveals the relationships between the endotracheal tube tip and the tracheal first bifurcation (carina). X-ray pictures may be and should be taken whenever an endotracheal tube is placed or
- 25 repositioned. Additionally, the tube placement may be verified through a fiber

optic bronchoscope, by a suction bulb, or through sending and receiving an acoustic signal. These methods are used to verify the initial placement of the endotracheal tube. There are no currently available means for continuous monitoring of the actual placement of the tube.

- 5 The advantages of fiber optic visualization were combined with the simple design of the laryngoscope as disclosed by several patents and scientific papers. Additionally, the use of visualization stylets which include means for seeing the airways during the insertion of an endotracheal tube have been described. However, there are no known methods for incorporating the
- 10 visualization means permanently into the anterior face of the endotracheal tube so that visualization of the airways can be accomplished during the insertion and continuously thereafter.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic isometric scheme of the tube of the invention incorporating three types of conduits;

Fig. 2 is a schematic isometric description of a portion of the anterior face of the tube of the invention into which a miniature video camera is incorporated;

Fig. 3 is a schematic description of the items commuting along the tube of the invention, related to the performance of inspection tasks.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

In accordance with the present invention, a multifunctional inspection tube is provided for collecting information about internal cavities and spaces in the body of a patient or an animal in association with the insertion of an inspection tube in the body. The multifunctional inspection tube is a modified medical tube such as an endotracheal tube, catheter, a gastric feeding tube. In accordance with the present invention the tube is equipped with means to examine both the positioning of the inspection tube with respect to body organs and the functional aspects of the body during and after the insertion. Thus, the tube of the invention may be used to perform not only customary medical treatment tasks of conveying gasses and or liquids to and from the penetrated organs, but also inspection tasks that examine the reaction to such treatment and otherwise the condition of the penetrated organs. The multifunctional inspection tube of the invention incorporates a means of receiving signals relating to the condition of the penetrated organs such as visual and audio signals by employing suitable sensors incorporated at or near the anterior face of a tube. The signals produced by the sensors are transmitted via wires or communication fibers running along the length of the tube to a connector or a wireless transmitter located at the posterior portion of the tube near its standard connector to the ventilation source, gastric tube feeder or urinary collecting device. The signals are received by a receiver containing a suitable signal conditioning means for subsequent processing, display, recording and or monitoring. The structural concept of the invention is better explained with reference to **Fig. 1**. A portion **20** of a multifunctional inspection tube of the

invention is shown, including an anterior face **22**. Channels and a conductor are associated with the wall of the tube. A totally embedded channel **24** runs along the length of the inspection tube within its wall, alongside an open recessed channel **26**. A conducting element **28** runs along the length of the tube without
5 being embedded in the wall of the tube, rather it is attached to the wall of the tube and occupies a space in the lumen of the tube. The conduit may be partially embedded in the tube or it may be inserted within a recess or it may be threaded within a totally embedded channel without being attached to the tube. Even in embodiments in which the lumen contains a conducting element
10 attached to the wall as described above, the lumen of the tube is still largely free for transferring liquids or gasses in both directions. With this respect, embodiment in which the channels and conducting elements embedded or wholly inserted in the wall may be preferable.

A typical feature of the multifunctional inspection tube is the
15 acquisition of internal images of the body. For acquiring the images, an image sensor may be employed, such as a miniature electronic camera employing a CCD or a CMOS chip incorporated in the anterior face of the inspection tube. In one embodiment, the camera is incorporated in a recess in the wall of the tube as described in **Fig. 2** to which reference is now made. A portion of an
20 inspection tube is shown, within the inner side **40** of which, a camera **42** is inserted in a recessed channel, protruding from the anterior face **44** of the tube. The signal of the camera is transmitted by a conducting element **46**, typically a copper wire or an optical fiber. The camera's lens is facing away from the tube. The signals arriving from the camera are subsequently fed to a receiver and
25 may be subsequently displayed on a screen, which may be a stand-alone mini

screen, an ordinary video screen, or a portion of the display screen ordinarily used to monitor the physiological parameters and well - being of the patient. In some embodiments of the invention, a fiber optical element running along the length of the tube is used to convey light to illuminate the field of view ahead of the anterior face of the inspection tube. Alternatively, a light source may be associated with the proximal face of the tube. Examples for light sources are miniature halogen lamps, light emitting diodes (LED), lasers, or any other kind of light-emitting source of suitable size. An alternative method of illumination is by constructing the inspection tube made of light - conducting material. In some
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embodiments of the invention, means for keeping the lens of the camera and /or other sensors clean and clear are employed. The airways, stomach or urinary bladder of an ill patient are often filled with secretions that may be thick and viscous. Thus, it is quite possible that the secretions may lodge on the lens and obscure its field of view, or on other sensors thereby modifying their responsiveness. To overcome such an obstacle, a constant or intermittent flow of air or physiological fluid is pumped through a channel in the tube's wall, whereby the outlet of the channel is aimed directly over and around the lens or the sensor's active surface. This flow may be generated by a simple flow source or by a device that is triggered to emit flow upon command from a human care giver, a timer or a software program that monitors the signal and determines when clearing action is required.

In general, the inspection tube is used as bi - directional conveying platform for various elements required for the fulfillment of its inspection tasks. This is described schematically in Fig. 3 to which reference is now made. Tube
25
52 receives activation energy **54** of one or several types on its rear end, and

downloads information 56, raw or processed at the same end. At the anterior end 58, the tube receives signals 60 of one or several types, and spends energy 62 as will be elaborated later on.

In some embodiments of the invention, a microphone is employed in the tube. Such a microphone can be incorporated in the wall of the tube. Such a microphone receives acoustic signals from at least the vicinity of the tubes anterior, and transfers the signals, raw or processed to the rear of the tube for further downloading and processing.

A plurality of sensors can be effectively employed in the anterior face of the tube of the invention, the non exhaustive list includes cameras, video cameras, microphones, pressure transducers and thermal sensors. Gas sensors, for example sensors for particular gasses such as oxygen and carbon dioxide may also be employed. The energy required to activate such sensors is supplied by conduits of energy such as electric wires incorporated in the tube. In addition, auxiliary energy can be supplied to the vicinity of the anterior face of the tube for the purpose of cleaning and clearing the sensors active facets by flushing them with cleaning media such as gases, humidified air or oxygen, or liquids, typically a physiological solution, through channels in the wall of the tube. Liquids and or gases for flushing are energized and conducted typically via a totally embedded channel. The inspection tube of the invention may be used alone or in combination with other catheters and tubes that are ordinarily inserted into a body organ, tract or cavity such as the esophagus, the stomach, the intestine, the colon, the urinary bladder, the pleural space, lung airways and/or the peritoneal cavity. The present technology may be applied in various medical practices and treatments such as: artificial ventilation of the lung,

feeding or removing the content of the stomach, draining urine from the bladder, draining the gas and feces from the colon, and draining or injecting into a surgically accessed cavity such as the pleural space, or the peritoneal cavity.

5 The sensors of the tube transmit one or more signal types, which are either preprocessed in the sensor for example on the CCD chip, or may be sent raw, to be further processed by analog or digital circuits to yield information relating to the status of the organ or body cavity inspected. The receiving and or processing devices such as, monitors, displays, storage means, analyzers,
10 DSP processors, computers and generators of alarm signals are typically connected by one or a plurality of connectors to the tube. The tube of the invention may be used for insertion through orifices such as the nose, mouth, urethral meatus, rectum, or a surgical incision.

 The transmission of raw or preprocessed signals is affected through
15 conductors along the tube such as wires or optical fibers, which connect to a connector at the rear of the tube. A wireless transmitter or transceiver may be applied anywhere suitable on the tube, typically at the rear, for communicating with a console containing a receiver and processor and or a control module.

 The inspection tube of the invention may also be used to detect
20 changes in indications of vital functions of a patient. Accordingly, image and acoustic signal are being detected, processed and compared to a reference base picture or sound structure. An alarm is set as soon as certain changes in the indication pass a predetermined threshold. For example, the accumulation of secretions, or development of excessive or diminished lung noises are
25 abnormal.

CLAIMS

1. A tube for inspecting internal organs of a body wherein at least one sensor is incorporated in said anterior face of said tube and
5 wherein:
- at least one conduit of energy to activate said at least one sensor is associated with the wall of said tube;
 - at least one conducting element for transmitting signals of said at least one sensor to the rear end of said tube,
10 and
 - at least one receiver for said signals.
2. A tube for inspecting internal organs as in claim 1 and wherein the wall of said tube comprises a channel.
15
3. A tube for inspecting internal organs as in claim 2 and wherein the wall of said tube comprises a totally embedded channel.
4. A tube for inspecting internal organs as in claim 2 and wherein the
20 wall of said tube comprises a recessed channel.
5. A tube for inspecting internal organs as in claim 1 and wherein a lighting element is associated with said anterior face of said tube.

6. A tube for inspecting internal organs as in claim 5 and wherein said lighting element is an optical fiber running along the wall said tube.
- 5 7. A tube for inspecting internal organs as in claim 5 and wherein said lighting element is a light emitting source.
8. A method for inspecting internal organs of a body wherein at least one sensor is incorporated in an anterior face of a tube and
10 wherein:
- energy is supplied to said anterior face of said tube for at least activating said at least one sensor by way of at least one conductor running along said tube;
 - signals are transmitted from said at least one sensor to a
15 rear of said tube, and
 - said signals are fed into a receiver of said signals.
9. A method for inspecting internal organs of a body as in claim 8 and wherein some of said energy supplied to said anterior face of
20 said tube is used for keeping a sensor clear.
10. A method for inspecting internal organs of a body as in claim 8 and wherein said signals are raw.

11. A method for inspecting internal organs of a body as in claim 8
and wherein said signals are pre processed.
12. A method for detecting changes in indications of vital functions
5 of a patient, wherein sensors of an inspection tube in said patient
send signals which when interpreted as passing a certain
predetermined threshold of deviation set an alarm on.

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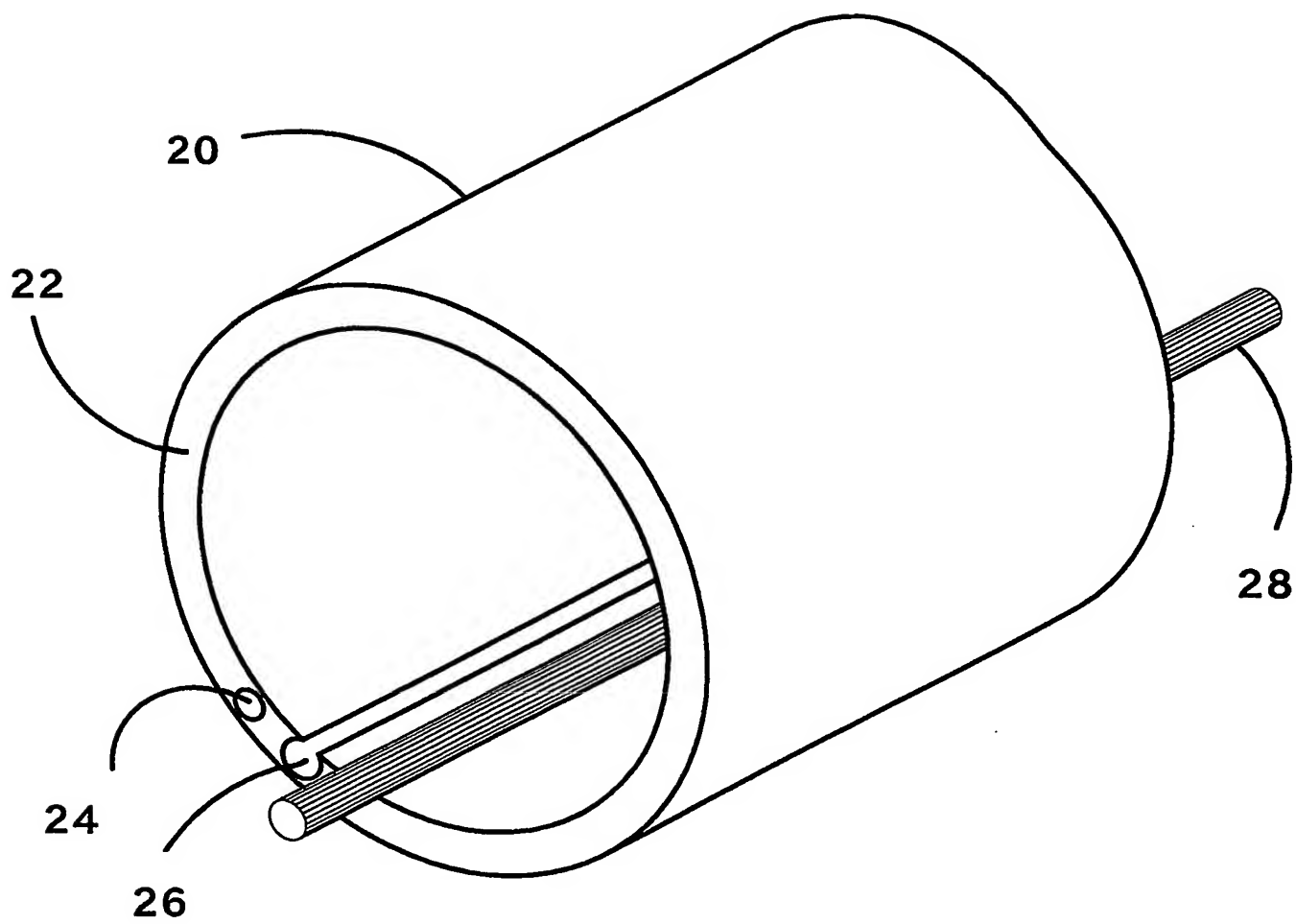


Fig. 1

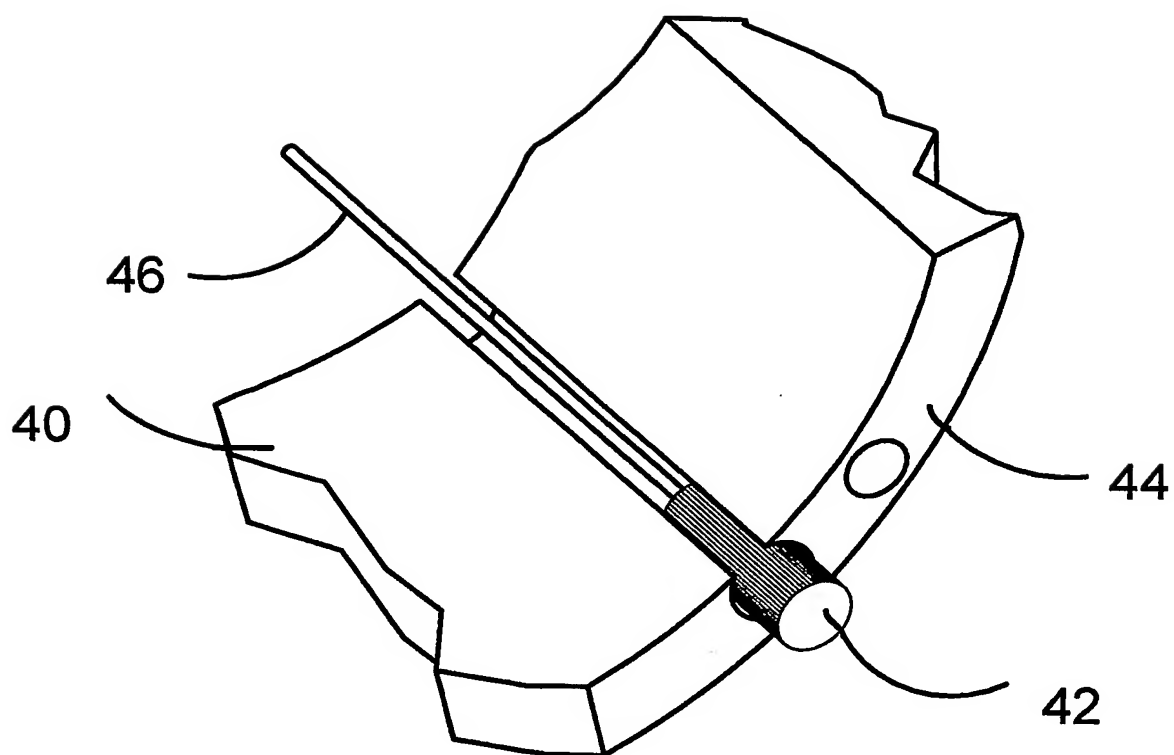


Fig. 2

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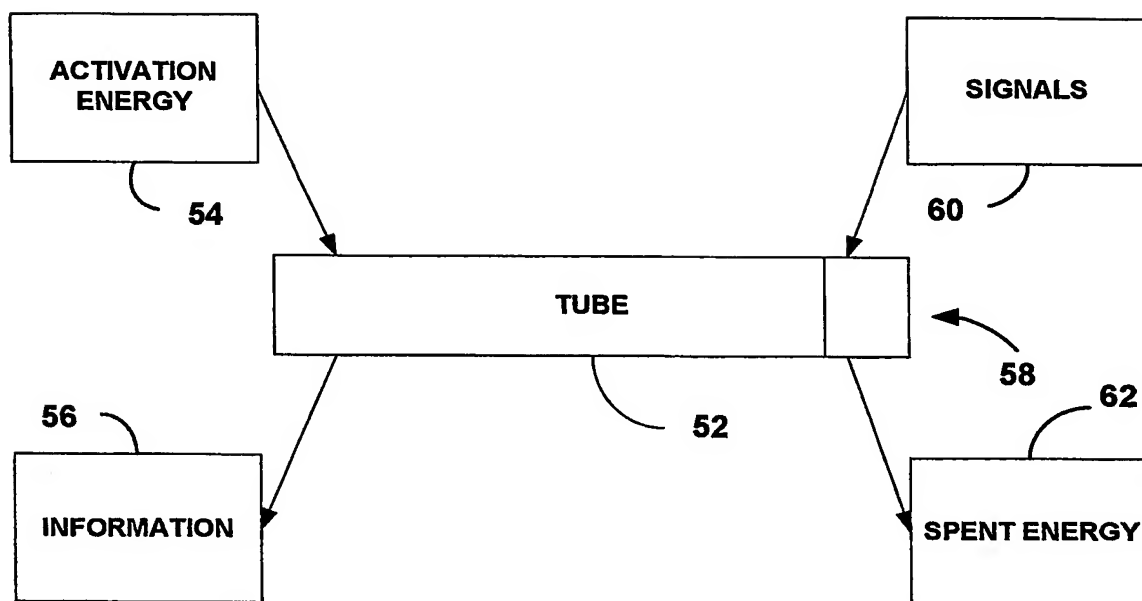


Fig. 3

PCT/IL 03/00797

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B1/012 A61B1/05 A61B1/267

IPC 7 A61B A61M

WPI Data, EPO-Internal, PAJ

X,P	WO 02 085194 A (POWER MEDICAL INTERVENTIONS IN) 31 October 2002 (2002-10-31) page 9, line 23 -page 11, line 30; figures 4A,4B,5	1-7
X	US 2002/072680 A1 (WILLIAMS JONATHAN ET AL) 13 June 2002 (2002-06-13) paragraphs '0033!,'0036!-'0038!; figures 1,3	1-6
X	US 6 266 547 B1 (SHEPHERD JOHN M ET AL) 24 July 2001 (2001-07-24) column 2, line 57 -column 3, line 53; figure 1	1-5,7

—/—

☒ Patent family members are listed in annex.

*& document member of the same patent family

Dervé, G

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IL 03/00797

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 28784 A (KELLEHER BRIAN S) 22 December 1994 (1994-12-22) page 5, line 34 -page 7, line 14; figure 1 page 11, line 34 -page 12, line 6; figure 15	1-3,5-7
X	US 6 164 277 A (MERIDETH JOHN H) 26 December 2000 (2000-12-26)	1
A	column 5, line 7-28; figure 1	2
A	EP 0 712 601 A (STORZ KARL GMBH & CO) 22 May 1996 (1996-05-22) column 4, line 22-59; figures 1-3,5	1-7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 03/00797

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 8-12
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IL 03/00797

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
WO 02085194	A	31-10-2002	EP	1381302 A1	21-01-2004
			WO	02085194 A1	31-10-2002
			US	2002165444 A1	07-11-2002
US 2002072680	A1	13-06-2002	US	2002072679 A1	13-06-2002
			AU	2027102 A	24-06-2002
			WO	0247751 A2	20-06-2002
US 6266547	B1	24-07-2001	AU	764324 B2	14-08-2003
			AU	5703899 A	27-03-2000
			AU	761841 B2	12-06-2003
			AU	6025799 A	27-03-2000
			CA	2343207 A1	16-03-2000
			CA	2355337 A1	16-03-2000
			EP	1112020 A1	04-07-2001
			EP	1109487 A1	27-06-2001
			JP	2002524121 T	06-08-2002
			JP	2002524122 T	06-08-2002
			WO	0013575 A1	16-03-2000
			WO	0013576 A1	16-03-2000
			US	6263223 B1	17-07-2001
			US	2002028990 A1	07-03-2002
			AU	754324 B2	14-11-2002
			AU	5907799 A	27-03-2000
			AU	754659 B2	21-11-2002
			AU	6025699 A	27-03-2000
			CA	2343192 A1	16-03-2000
			CA	2343635 A1	16-03-2000
			EP	1121047 A1	08-08-2001
			EP	1112018 A1	04-07-2001
			JP	2002524118 T	06-08-2002
			JP	2002524123 T	06-08-2002
			WO	0013567 A1	16-03-2000
			WO	0013577 A1	16-03-2000
			US	6253098 B1	26-06-2001
			US	6256524 B1	03-07-2001
WO 9428784	A	22-12-1994	US	5486154 A	23-01-1996
			AU	683476 B2	13-11-1997
			AU	7058894 A	03-01-1995
			CA	2162675 A1	22-12-1994
			EP	0705069 A1	10-04-1996
			JP	8510676 T	12-11-1996
			US	RE37772 E1	25-06-2002
			WO	9428784 A1	22-12-1994
US 6164277	A	26-12-2000	NONE		
EP 0712601	A	22-05-1996	US	4877016 A	31-10-1989
			EP	0712601 A1	22-05-1996
			CA	1318968 C	08-06-1993
			EP	0494134 A1	15-07-1992
			WO	9104703 A1	18-04-1991